

Behavioral and Social Sciences Research Coordinating Committee

Minutes of April 13, 2001 Meeting

Attendance

The NIH Behavioral and Social Sciences Research Coordinating Committee met on April 13, 2001 from 9:00 to 11:00 a.m. in the Gateway Building, Room 525. Virginia Cain (OD/OBSSR) presided. Members and alternate members in attendance were: Judy Auerbach (OD/OAR), Christine Bachrach (NICHD), Pat Bryant (NIDCR), Emmeline Edwards (NINDS), Suzanne Heurtin-Roberts (NCI), Morgan Jackson (NCCAM), Peter Kaufmann (NHLBI), Raynard Kington (OD/OBSSR), Minda Lynch (NIDA), Susan Martin (NIAAA), Georgeanne Patmios (OD/OBSSR), Janice Phillips (NINR), Lana Shekim (NIDCD), Paula Skedsvold (OD/OBSSR), Susan Stark (NIAMS), Richard Suzman (NIA), and Charles Wells (NIEHS).

Sangeeta Panicker (APA) attended as a guest.

Discussion of “Third-Party Information in Research”

Background. A researcher at the Virginia Commonwealth University was attempting to build a database on the health of twins, and sent a 25-page questionnaire to twins in the state. The father of one twin opened his daughter's mail and was alarmed that she was being asked questions about his mental health and genitalia. After contacting the researcher and IRB, he raised his concerns with the Office for Protection from Research Risks (OPRR), now the Office of Human Research Protections (OHRP). OPRR investigated and in January 2000, found that the IRB failed to follow federal regulations governing research involving human subjects. Specifically, the IRB did not consider that the study included the collection of individually-identifiable, private information on family members, thereby making these persons “human subjects” under the Common Rule and requiring that informed consent be obtained or waived by the IRB.

Issue. OHRP's finding seemed to imply a different interpretation of “human subject” than that historically used by both investigators and IRBs. Although information concerning third parties is considered confidential and protected by investigators, third parties generally have not been viewed as research subjects requiring informed consent.

NIH Activities. In response to an invitation by Greg Koski, Director, OHRP, as well as inquiries from investigators whose research had been affected by the OHRP finding, the NIH formed a subcommittee of the Trans-NIH Bioethics Committee (T-NBC) to examine the issues and provide advice to investigators and OHRP. Jim Hanson (NCI) and Sarah Carr (Office of Science Policy) co-chair this subcommittee.

NHRPAC Activities. At its April 9-10 meeting, the National Human Research Protection Advisory Committee (NHRPAC) invited Francis Collins and a panel to discuss the collection of family history information in genetics research. Following the discussion, a working group was formed to look closely at the issues and develop recommendations for NHRPAC. One task of the group is to examine the definition of “human subject” in the Common Rule. A new member of the NHRPAC, Felice Levine (Executive Director of the American Sociological Association) will serve on this working group. Dr. Levine also serves as Co-Chair of NHRPAC's Social and Behavioral Science Working Group.

Group Discussion. Discussion of these issues included: the topics being addressed by NHRPAC's Genetics Working Group; how this issue relates to “group rights”; “community consultation” activities; and the hope that the discussion of these issues will establish norms for proactive thinking. The group asked that OBSSR continue to ensure that when these issues are discussed, that the behavioral and social sciences community is involved, and that OBSSR keep

the NIH BSSR community informed about the direction in which the issue is going. For more information, contact Paula Skesvold in OD/OBSSR at 301-435-6780.

BSSR Components of IC Health Disparities Research Plans: NIAMS

For the past few months, individual committee members have presented the behavioral and social science components of their respective IC's Health Disparities Strategic Plans. At this meeting, Dr. Susan Stark presented NIAMS' plan.

The NIAMS Strategic Plan for Reducing Health Disparities is available at <http://www.nih.gov/niams/strategicplanhd/strategicplanhd.htm>. Key points include initiatives on osteoarthritis and outreach, and the December 2000 conference on Health Disparities in Arthritis & Musculoskeletal & Skin Diseases which reviewed current knowledge about health disparities in arthritis and musculoskeletal and skin diseases and promoted new research opportunities and approaches to eliminating disparities in the incidence and course of these diseases in ethnic groups at increased risk (see also <http://www.nih.gov/niams/reports/hdreg.htm>). Also, NIAMS is collaborating with FIC and other Institutes on a September 5-7, 2001 international conference on stigma as it relates to public health, which will examine the causes and consequences of stigma, both in the developing world and the United States (see also <http://www.nih.gov/fic/news/stigmaconference.html>).

Data and Safety Monitoring Boards (DSMB) for Behavioral Interventions

NIH policy is that all NIH-sponsored or -conducted clinical trials should have in place a system for appropriate oversight and monitoring to ensure the safety of participants and the validity of the data (NIH Policy for Data Safety and Monitoring, NIH Guide, June 10, 1998 <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>). Also, beginning with the October 2000 receipt date, investigators must submit a monitoring plan for phase I and II clinical trials to the funding IC before the trial begins. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

Since behavioral intervention studies do come under this policy, IC staff expressed interest in devoting a future BSSR CC meeting to this topic. In particular, IC staff would like examples of this policy as applied to behavioral trials, and a discussion of any special issues that come up when applying this policy to BSSR studies. Dr. Peter Kaufmann, NHLBI, spoke about his experience with DSMBs and how they have been very good for NHLBI behavioral trials. OBSSR was asked to disseminate the policies to the BSSR CC and arrange for this to be discussed at a future BSSR CC meeting with a researcher who has served on a DSMB for a behavioral trial.

Announcements

- The report from the June 2000 NIH conference on "Towards Higher Levels of Analysis: Progress and Promise in Research on the Social and Cultural Dimensions of Health" was posted on the OBSSR website and comments (not many) were received. Revisions to the report have been made and the final report will be available at: http://obssr.od.nih.gov/Conf_Wkshp/higherlevel/sociocultural-draft.pdf. Hard copies of the report will also be available. OBSSR emailed the IC Directors asking each to nominate Program Staff to serve on a planning committee to develop a Program Announcement as a follow up to the conference.
- Dr. Kington will be briefing IC Councils this round and next on the NAS report *New Horizons in Health: An Integrative Approach*.
- Dr. William Julius Wilson of Harvard University will be giving the NIH Director's Lecture on May 16 from 3-4 p.m. in Masur Auditorium. He will speak on *Welfare, Children and Families: The Impact of Welfare Reform in the New Economy*. Dr. Wilson will address

questions about the impact of the robust economy on the positive outcomes of the 1996 welfare reform bill and the claims that welfare reform has been a success. He will present findings on the characteristics of families that have been sanctioned for not following welfare rules, and on the experiences and challenges of the families who have left the welfare rolls. Given these findings, Dr. Wilson will then reflect on the possible consequences of an economic slowdown and also address the policy implications suggested by economic changes. Dr. Wilson's other work has examined the impact of high neighborhood joblessness rates (in some cases, over sixty percent of adults in the neighborhood without jobs) and the devastating consequences for the residents of these communities and larger society.

- Dr. Troy Duster of UC Berkeley and NYU, will be speaking at the NIH Wednesday Afternoon Lecture Series, May 9, 3:00 pm in Masur Auditorium (Building 10). He has worked in the areas of the social implications of genetic research, particularly with respect to racial/ethnic communities, and multiculturalism and affirmative action, among other things. His early work was on "deviance" (as it used to be called), in particular the social construction of drug and alcohol use and abuse. Dr. Duster's lecture is sponsored by the Behavioral and Social Science Interest Group and the AIDS Interest Group.
- Virginia Cain (OD/OBSSR) announced that OBSSR has begun developing a workshop on racial bias and health planned for April 18-19, 2002 at Natcher. IC staff interested in joining the planning group may contact Dr. Cain at 2-1146.
- There will be a STEP (Staff Training in Extramural Programs) session on *The Science of Aging: Sustaining Independence* on April 17 from 8:30 - noon in Wilson Hall. Dr. Kington will be one of the speakers.
- There are several openings on *The National Committee for Vital and Health Statistics* (NCVHS). Nominees from academia in a wide range of disciplines will be considered. The notice soliciting nominations is at <http://www.ncvhs.hhs.gov/010316fr.htm>. For an overview of the NCVHS, see <http://www.ncvhs.hhs.gov/>.
- Dr. Morgan Jackson of NCCAM announced that the NCCAM Strategic Plan to Address Racial and Ethnic Health Disparities will be presented to the NCCAM Advisory Council end-May, after which it will be posted on the web. (See <http://nccam.nih.gov/strategic/text.htm> for the strategic plan).
- The Cultural and Qualitative Research Interest Group will meet on April 23 to make the final edits on the "Qualitative Report." This will be presented at a future BSSR CC meeting.
- Dr. Richard Suzman of NIA announced that interested Program Staff may contact him for multiple copies of a beta version of a CD-ROM on *Minority Aging Research Datasets* developed by ICPSR's National Computerized Data on Aging (NACDA). As discussed at the March meeting, this CD-ROM is being developed to be a unique and easily accessible CD-ROM of datasets related to minority aging processes valuable for analyses of health disparities within and across minority groups; to promote research on minority aging by fostering use of the CD-ROM by both experienced and inexperienced researchers; and to stimulate ideas for research projects and publications based on the use of the dataset collection. Contact Dr. Suzman at Suzman@nih.gov.
- Dr. Suzman also invited other ICs to contact him if there is interest in proposing new modules to the NIA Health and Retirement Study (U01, Cooperative Agreement). The group talked about presenting the HRS at a future BSSR CC meeting, including the procedures to propose new experimental modules.

- The National Research Council and the Institute of Medicine will hold a one-day symposium on May 23 to explore what we currently know about the influence of social and behavioral factors in health and disease, and the priority investments necessary to advance the field and support future research and interventions. The symposium will focus on the findings of the following NIH-funded reports: 1) *The Aging Mind: Opportunities in Cognitive Research*; 2) *Bridging Disciplines in the Brain, Behavioral, and Clinical Sciences*; 3) *Health and Behavior: The Interplay of Cells, Self and Society*; 4) *From Neurons to Neighborhoods: The Science of Early Childhood Development*; 5) *New Horizons in Health: An Integrative Approach*; and 6) *Promoting Health: Intervention Strategies from Social and Behavioral Research*.
- Judy Auerbach of OD/OAR announced that OAR will again be sponsoring a prevention science initiative to support HIV-related projects. More information will be shared with the IC AIDS Coordinators. Projects for OAR funding support will be sent to OAR through the IC Directors. There is \$5 million available this year.

Next BSSR Lectures

NICHD Study of Early Child Care

Jay Belsky, Ph.D.

Visiting Professor of Psychology

University of London

Birkbeck College

April 17, 2001, 9 a.m.

Neuroscience Building, Conference Room C

NIH Director's Lecture: *Welfare, Children and Families: The Impact of Welfare Reform in the New Economy*

William Julius Wilson, Ph.D.

Harvard University

May 16, 2001, 3-4 p.m.

Masur Auditorium

Sleep, Circadian Rhythms, and Cognitive Performance

Mary Carskadon, Ph.D.

Brown University

David F. Dinges, Ph.D.

University of Pennsylvania

May 21, 2001, 9-10:30 a.m.

Building 1, Wilson Hall

Next BSSR CC meeting

May 11, 2001 9-11 a.m.

Gateway Building, Room 525

7201 Wisconsin Avenue, Bethesda MD